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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|------------------------------------|---|------------------------------|
| In re patent application of: |) | Before the Examiner: |
| Charles L. Branch et al. |) | Pedro Philogene |
| |) | |
| Application Serial No.: 10/698,702 |) | Group Art Unit: 3733 |
| |) | |
| Filed: October 31, 2003 |) | Ref. No.: MSDI-186/ PC365.07 |
| |) | |
| INTERBODY FUSION GRAFTS |) | |
| AND INSTRUMENTATION |) | |

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES
TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. §1.131)**

We, Charles L. Branch, Mingyan Liu, Lawrence M. Boyd and Loic Josse, hereby declare as follows:

1. We are each listed as a joint inventor of the subject matter disclosed and claimed in the subject patent application (hereafter the "Invention").
2. The subject application claims priority to and is a continuation of U.S. Patent Application Serial No. 10/645,413 filed on August 21, 2003, which is a continuation of U.S. Patent Application Serial No. 09/698,623 filed on October 27, 2000 and issued as U.S. Patent No. 6,610,065, which is in turn a divisional of U.S. Patent Application Serial No. 09/181,353 filed on October 28, 1998 and issued as U.S. Patent No. 6,174,311.
3. This Declaration is being provided to establish a date of conception and reduction to practice of the Invention in the United States on a date prior to August 3, 1998, which is the purported effective filing date of U.S. Patent No. 6,258,125 to Paul et al. that was cited in a non-final Office Action mailed to the Applicant on September 8, 2006 in the subject patent application.
4. On a date prior to August 3, 1998, the Invention was conceived of by the joint inventors.
5. On a date prior to August 3, 1998, the Invention was successfully reduced to practice in the United States.
6. To evidence conception and reduction to practice of the Invention, attached hereto is an Invention Disclosure that includes drawings and a description of the Invention which

correspond to the subject matter disclosed and claimed in the subject patent application. The dates listed on the Invention Disclosure have been blacked out, as well as dimensional data associated with the Invention. However, we declare that the "Date of Conception" and the "Date Constructed" occurred prior to August 3, 1998.

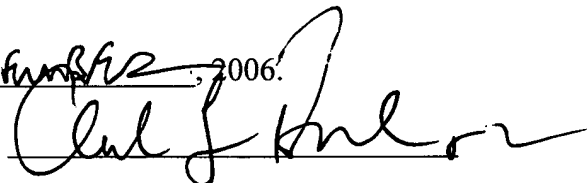
7. On a date prior to August 3, 1998 and shortly after the Invention was reduced to practice, the Invention was tested in the United States.

8. We declare that the "Date First Tested" listed on the Invention Disclosure occurred prior to August 3, 1998.

9. Shortly after construction and testing of the Invention, the Invention Disclosure was forwarded to the law firm of Woodard, Emhardt, Naughton, Moriarity & McNett for preparation of a patent application.

10. A patent application disclosing and claiming the Invention set forth in the Invention Disclosure was filed with the U.S. Patent and Trademark Office on October 28, 1998. (U.S. Patent Application Serial No. 09/181,353; issued as U.S. Patent No. 6,174,311).

WITNESS Declarant's hand this 14 day of NOVEMBER, 2006.


Charles L. Branch

WITNESS Declarant's hand this _____ day of _____, 2006.

Mingyan Liu

WITNESS Declarant's hand this _____ day of _____, 2006.

Lawrence M. Boyd

WITNESS Declarant's hand this _____ day of _____, 2006.

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WITNESS Declarant's hand this _____ day of _____, 2006.

Charles L. Branch

WITNESS Declarant's hand this 8 day of November, 2006.

Mingyan Liu

WITNESS Declarant's hand this _____ day of _____, 2006.

Lawrence M. Boyd

WITNESS Declarant's hand this 8 day of November, 2006.

Loic Josse

correspond to the subject matter disclosed and claimed in the subject patent application. The dates listed on the Invention Disclosure have been blacked out, as well as dimensional data associated with the Invention. However, we declare that the "Date of Conception" and the "Date Constructed" occurred prior to August 3, 1998.

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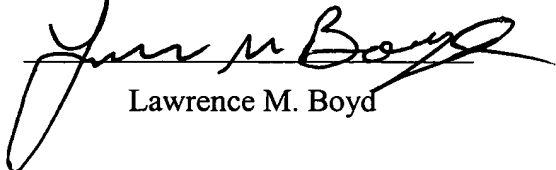
WITNESS Declarant's hand this _____ day of _____, 2006.

Charles L. Branch

WITNESS Declarant's hand this _____ day of _____, 2006.

Mingyan Liu

WITNESS Declarant's hand this 14th day of November, 2006.


Lawrence M. Boyd

WITNESS Declarant's hand this _____ day of _____, 2006.

**INVENTION DISCLOSURE**Disclosure No. 00014

Project No. _____

Sheet 1 of 23

| | | | | |
|---|--------------------------------|--|-----------------------------------|--|
| Title of Invention Impacted Bone PLIF implant and instrumentation | | | Project No. or Name | |
| Inventor(s) Charles L. Branch, M.D., Mingyan Liu, Lawrence M. Boyd, Loic Josse | | | Eng. Notebook No. & Pages | |
| Date Conceived [REDACTED] | Date Constructed [REDACTED] | Date First Tested [REDACTED] | Date Disclosed Outside Company | |
| <p>1. Describe what is new or different about the subject matter of this invention:</p> <p>Implant and instrumentation designs, which allow for a posterior lumbar interbody fusion (PLIF) procedure using a cortical bone implant, the implant insertion being achieved by impacting it into the disc space. The implant is cut from a human donor femur taking advantages of the load bearing structure and the given geometry of the femur bone. The versatile instrumentation design provides with a large variety of solutions for a PLIF surgery in terms of 1). Nerve root retraction, 2). Disc distraction and lordosis restoration, 3). Endplate preparation. A special inserter is designed for implant holding and insertion.</p> <p>2. Advantages of this invention over what was done before and problems solved:</p> <p>Increased safety by reducing posterior exposure to the disc and as a consequence reducing manipulation on the spinal neuro-structure. More efficient and reliable nerve root retraction and protection. More efficient and precise disc space restoration and endplate preparation. The implant design allows an optimal donor bone yield. The implant inserter provides with an X-ray marking for assessing intra-operatively the implant positioning.</p> <p>3. Describe your idea on attached sheets, providing whatever drawings or other sketches are necessary to completely describe the idea. Copies of engineering notebook sheets may be provided. All addendum sheets must be signed, witnessed and dated.</p> <p>See attached sheets.</p> | | | | |
| Inventor (Print/Type) Charles L. Branch, M.D. Address: <u>PO BOX 320</u> <u>ADVANCE, NC 27006</u> Citizenship: <u>USA</u> Signature: <u>[Signature]</u> Date: <u>[REDACTED]</u> | | Witness (Print/Type) <u>BRADLEY T. ESTES</u> Read, Witnessed and Understood Signature: <u>[Signature]</u> | | |
| Inventor Mingyan Liu Address: <u>41, rue de la Fontaine Grelot</u> <u>92340 Bourg-la-Reine, France</u> Citizenship: <u>Chinese</u> Signature: <u>[Signature]</u> Date: <u>[REDACTED]</u> | | Witness (Print/Type) <u>Debra Jourdan</u> Read, Witnessed and Understood Signature: <u>[Signature]</u> | | |
| Inventor Lawrence M. Boyd Address: <u>688 S. McLean Blvd</u> <u>Memphis, TN 38104</u> Citizenship: <u>U.S.</u> Signature: <u>[Signature]</u> Date: <u>[REDACTED]</u> | | | | |
| Inventor Loic Josse Address: <u>13 LA PLANA 115700 PALAUA</u> <u>FRANCE</u> Citizenship: <u>FRANCH</u> Signature: <u>[Signature]</u> Date: <u>[REDACTED]</u> | | | | |



INVENTION DISCLOSURE

Disclosure No. 00014

Project No. _____

Sheet 2 of 23

List patents, publications and products which you are aware of and which preceded your invention.

Related products:

Prantigan PLIF implant and instrumentation (AcroMed).

Ogival cage (Stryker)

Contact cage (Synthes)

Inventor Charles L. Branch

Date

Read, Witnessed and Understood

Inventor Mingyan Liu

Date

Read, Witnessed and Understood

Inventor Lawrence M. Boyd

Date

Inventor Loic Josse

Date



INVENTION DISCLOSURE

Disclosure No. 00014

Project No. _____

Sheet 3 of 23

Drawings and Description of Idea

See attached drawings.

Inventor Charles L. Branch Date

Read, Witnessed and Understood

Inventor Mingyan Liu Date

Read, Witnessed and Understood

Inventor Lawrence M. Boyd Date

Inventor Loic Josse Date

A handwritten signature in black ink, appearing to be 'Loic Josse', written over the signature line.

A solid black rectangular box used to redact the date for the signature of Loic Josse.

A solid black rectangular box, likely used to redact a date or other information at the bottom right of the page.

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| | | | | |
| FATHER | X | MOTHER | X | PATIENT |
| CONJUGATE SCALE | | DOWEL NO | | |
| X | X | PDOWELA136 | | |

PDOWELAA36

5/23

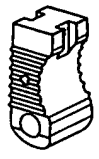
FINAL DRAWING

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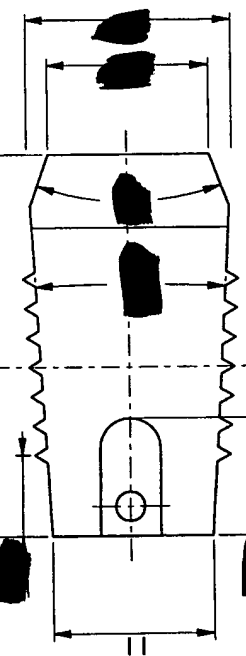
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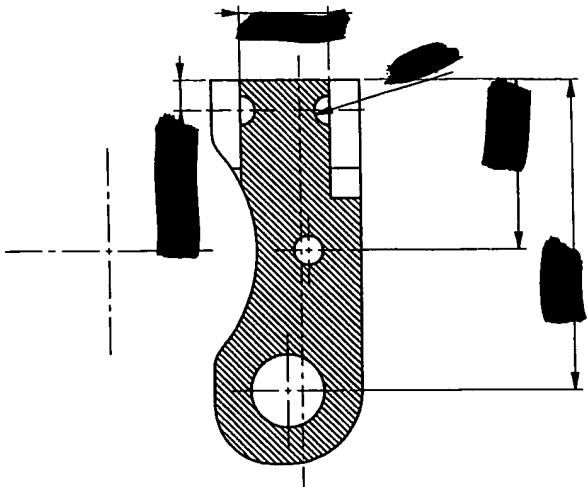
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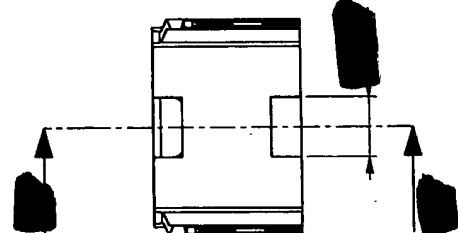
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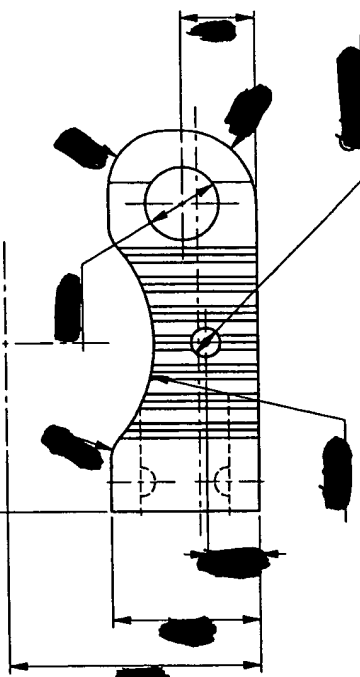


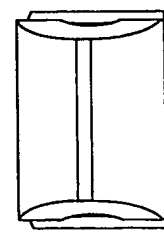
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SECTION CI-CI









FINAL DRAWING

| | | | | |
|--|--|--|--|---|
| SOFAMOR DANEK SOFAMOR DANEK USA 1000 PIRAMID PLACE, KENOSHA WI 53122 U.S.A. PH. 901-395-3133 FAX. 901-344-1535 | | DRAWN BY: JL APPROVED: _____ DATE: _____ | | CAT NO: _____ USED ON: _____ SYSTEM NAME: _____ |
| | | CHK BY: _____ DES ENGR: _____ MFG ENGR: _____ Q.A.: _____ | | PART NAME: IMPLANT 9x10x26 FINISH: _____ MATERIAL: _____ PART NO: _____ SCALE: _____ SHEET: 3 OF 3 |
| SOFAMOR DANEK MANUFACTURING 1000 PIRAMID PLACE, KENOSHA WI 53122 U.S.A. PH. 901-395-3133 FAX. 901-344-1535 | | | | |

Bone implant, 2nd Version

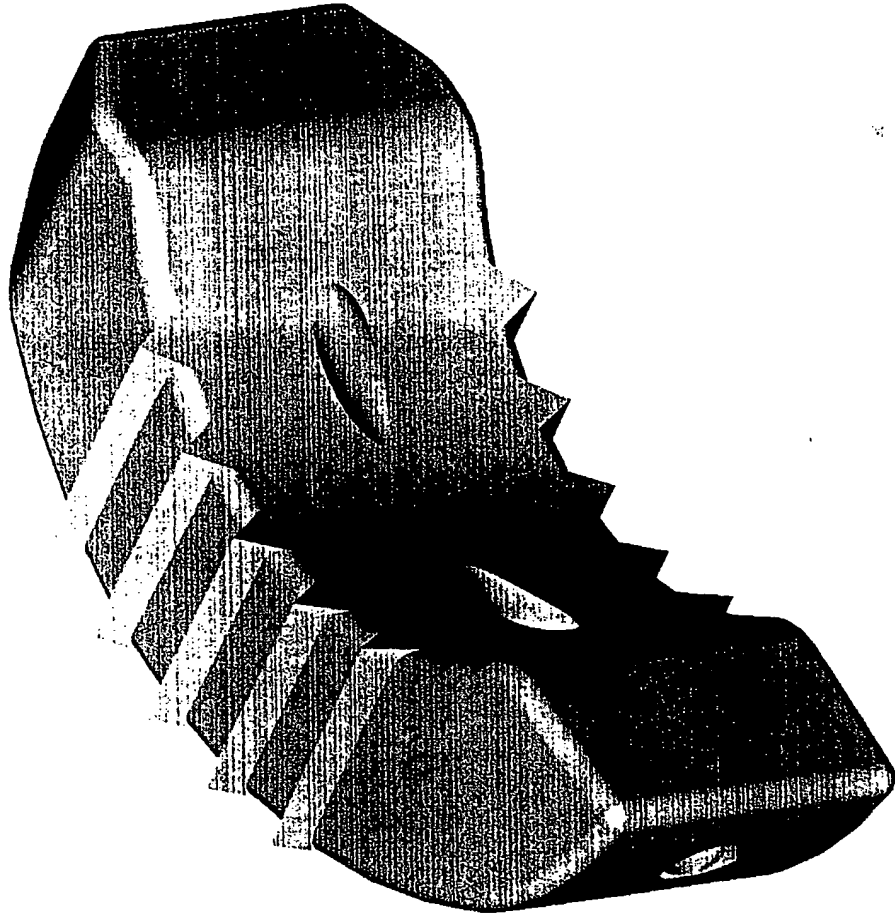
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ALL ALUMINIUM PARTS HARD ANODIZE COLOR NONE FINAL DRAWING

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Bone Implant, 3rd Version

cut from a human donor femur



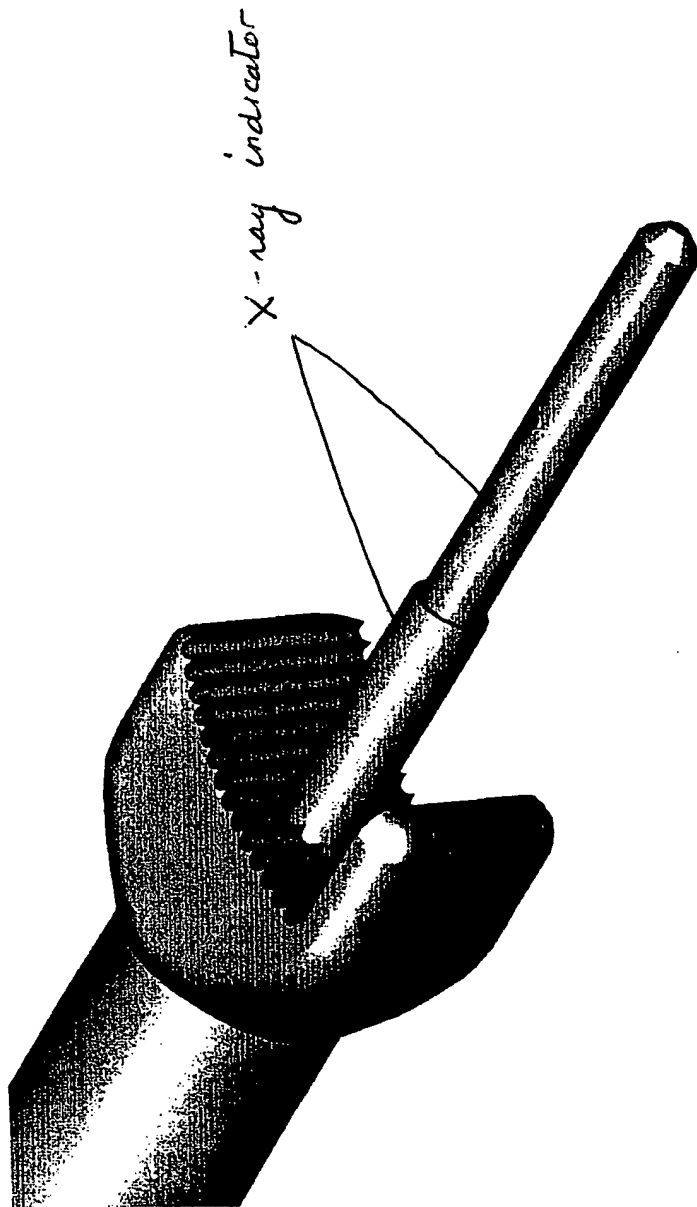
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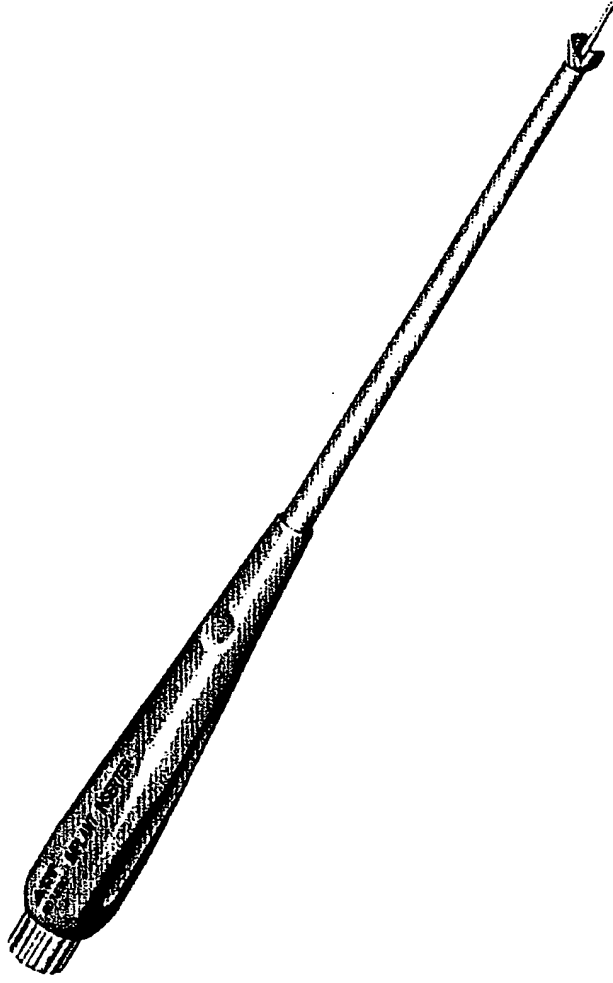
Implant Holding System. 3rd Version



Implant Insertion, 3rd Version

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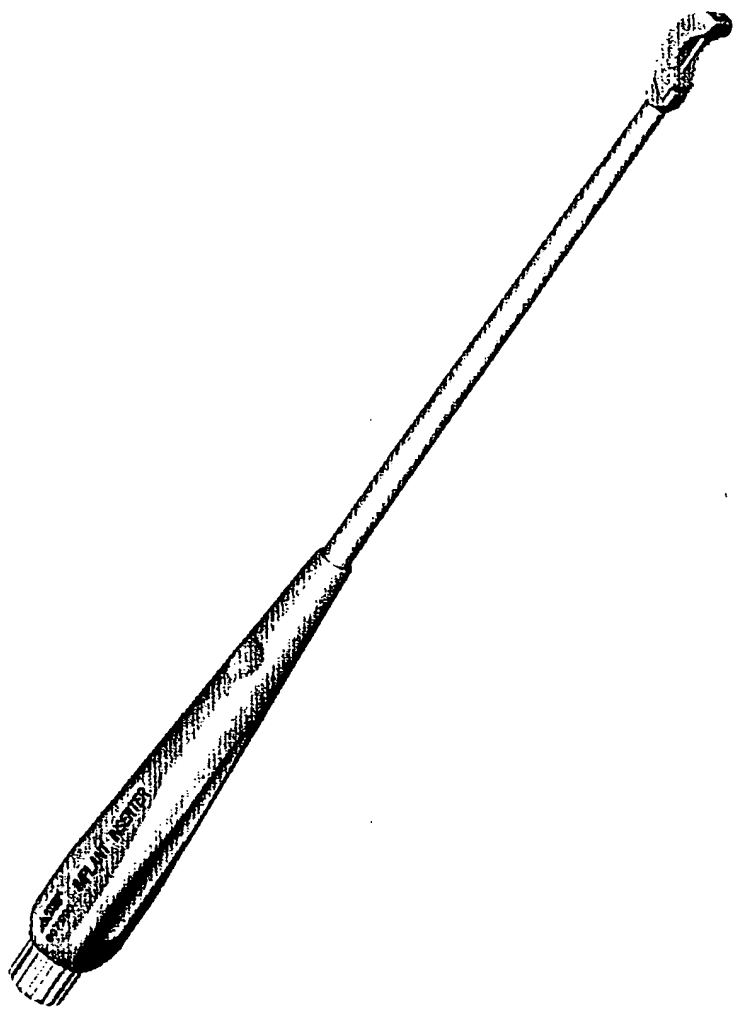
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Implant holding

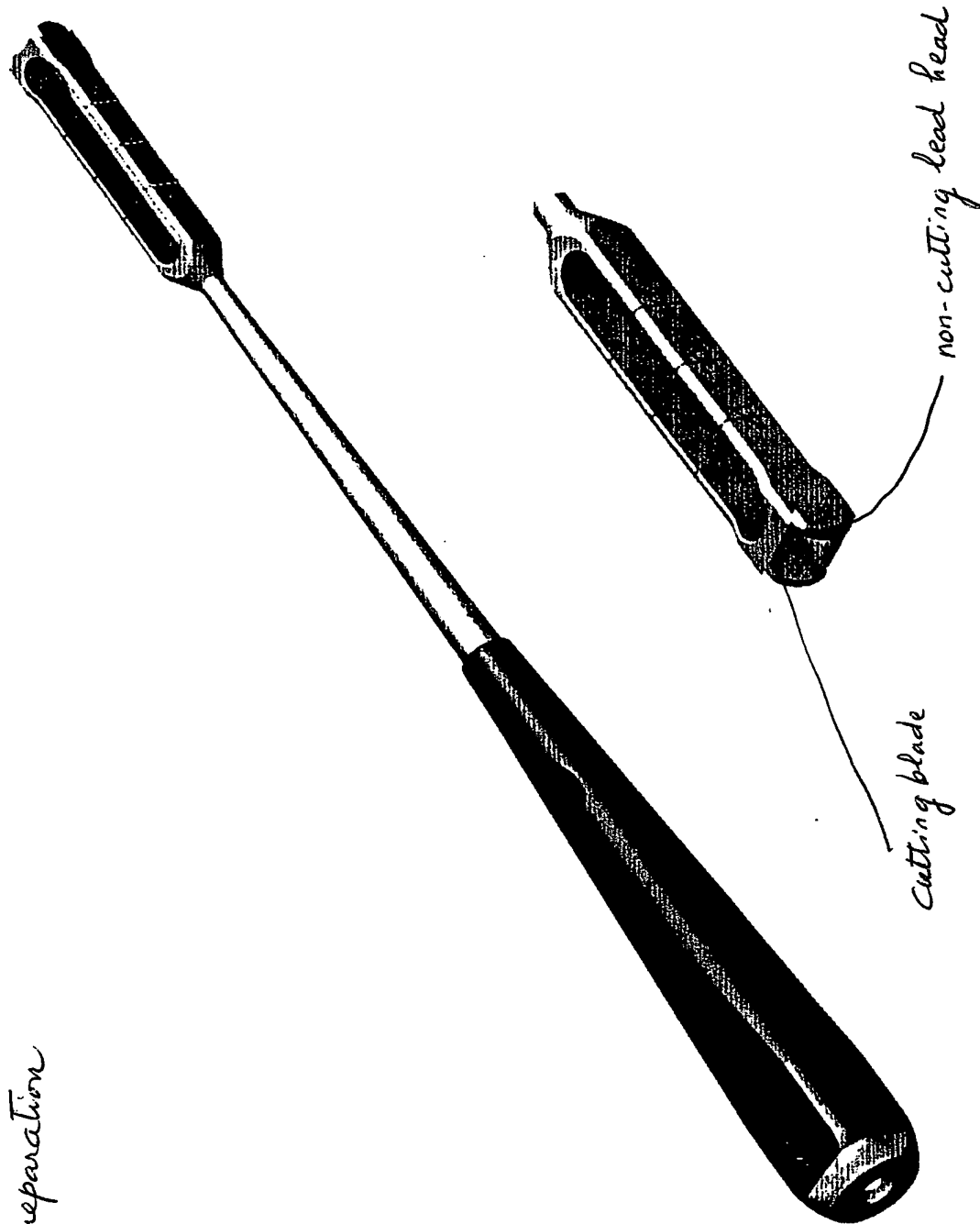


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Box chisel

implant specific instrument
for endplate preparation

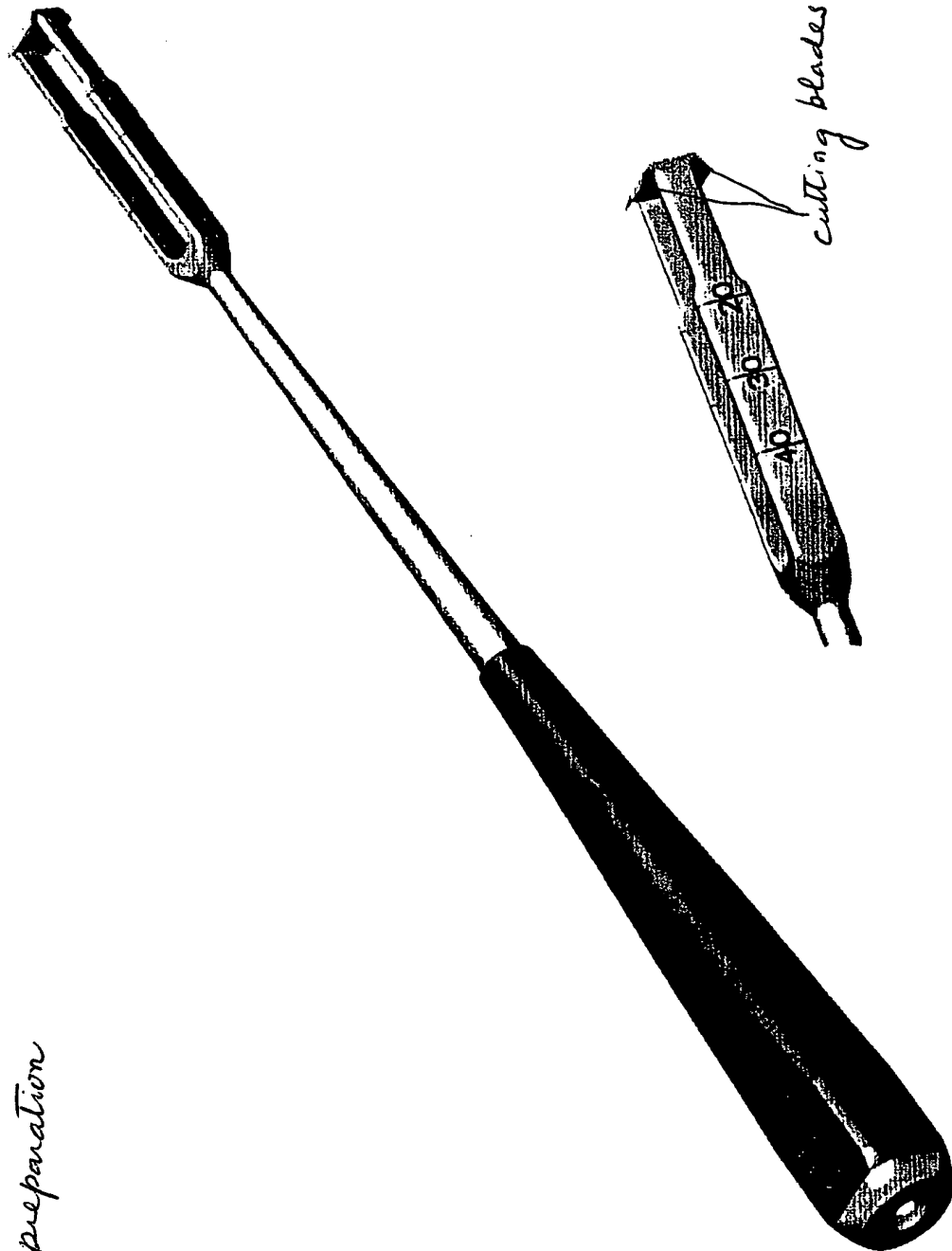


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Shaver

implant specific instrument
for endplate preparation



10419

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Slap-hammer

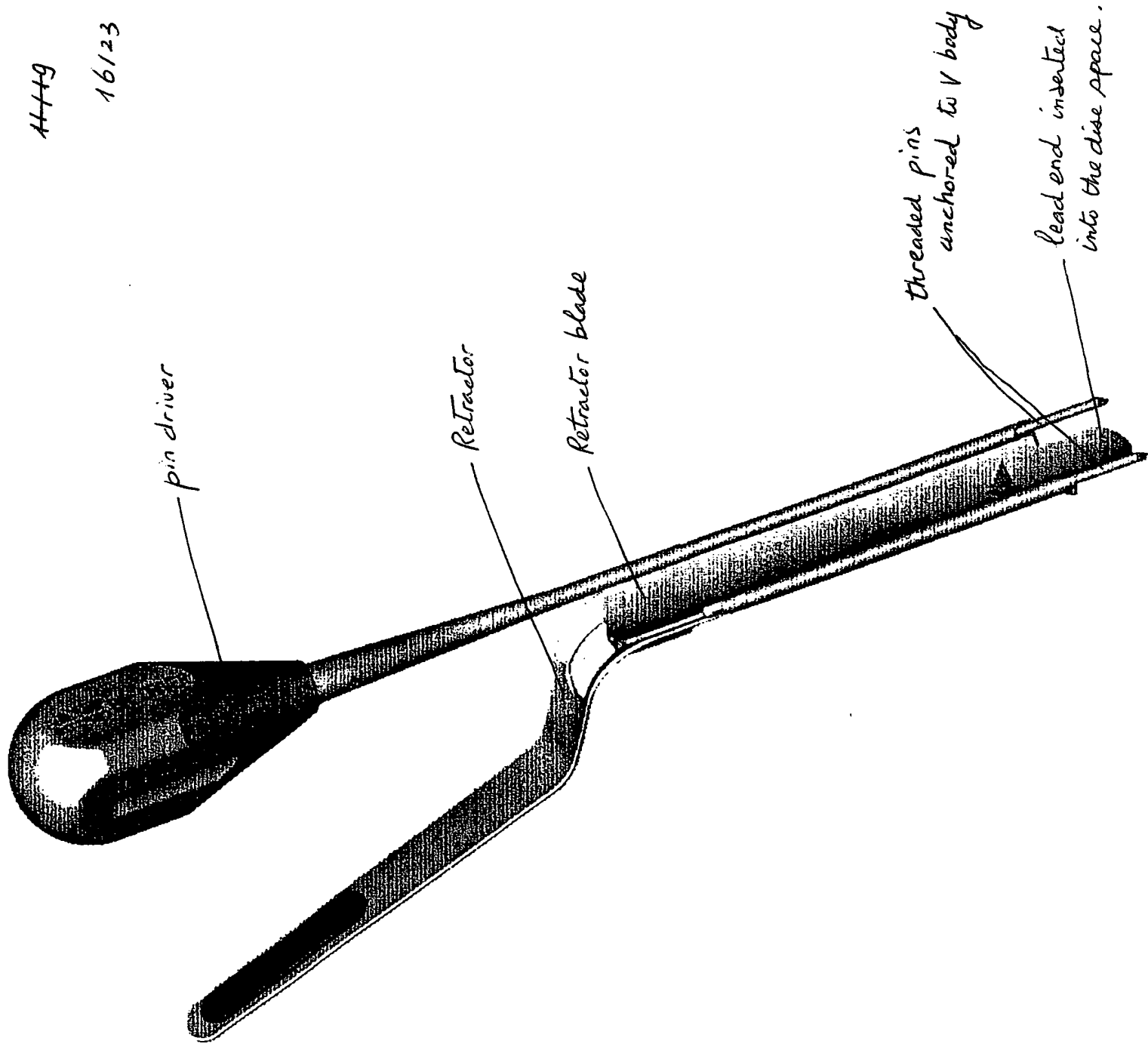
for endplate cutter extraction



Nerve Root Retractor

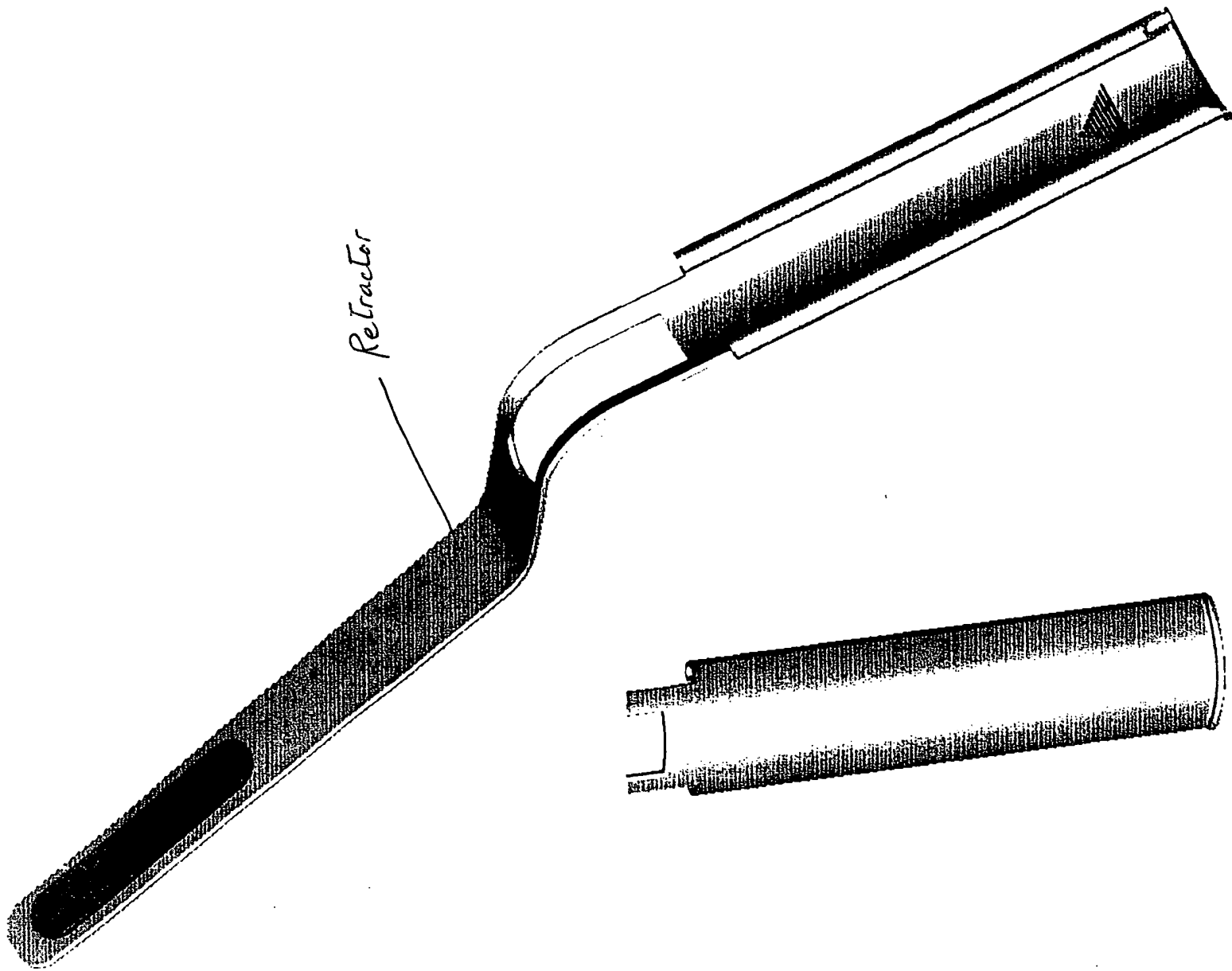
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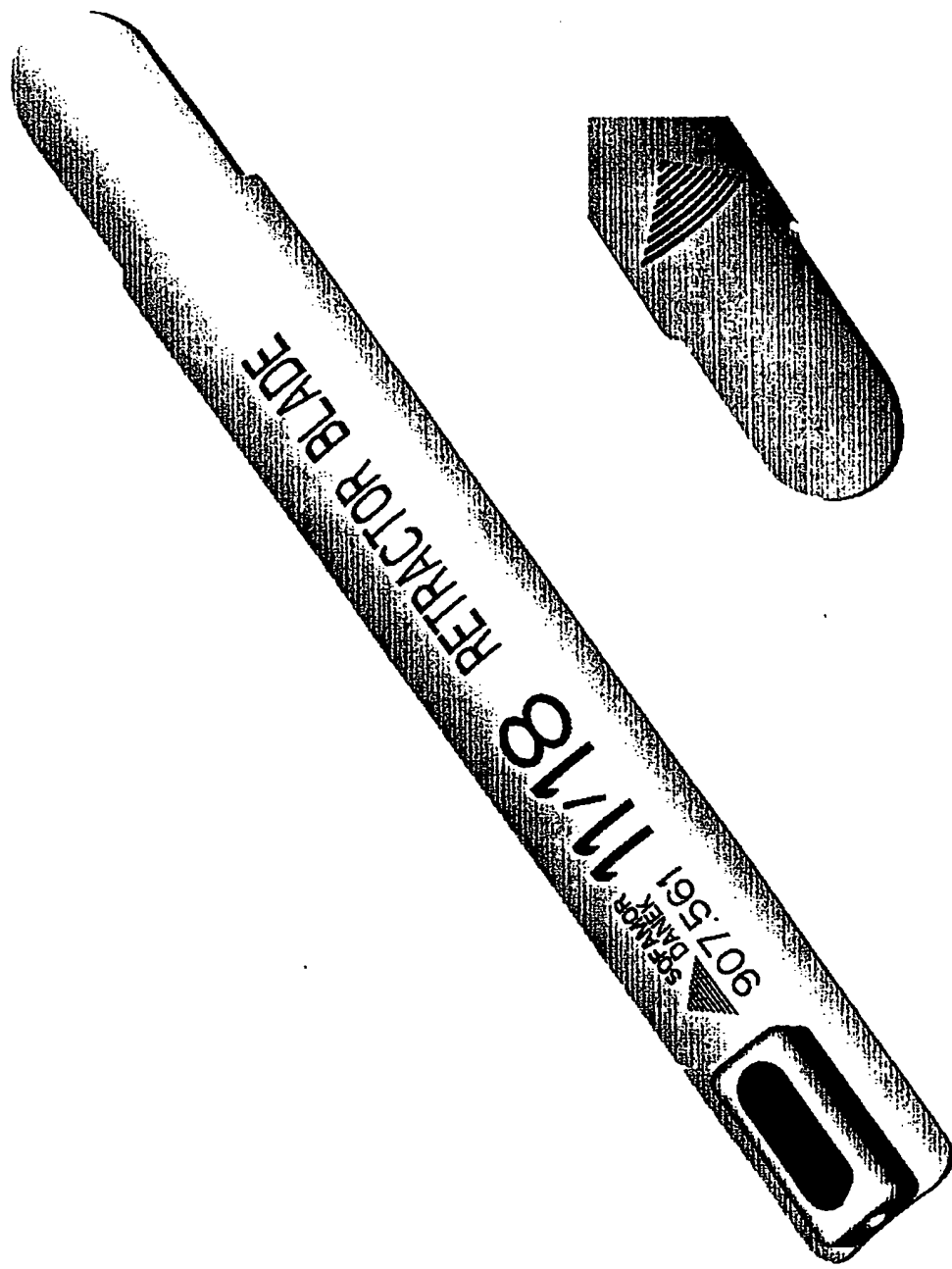
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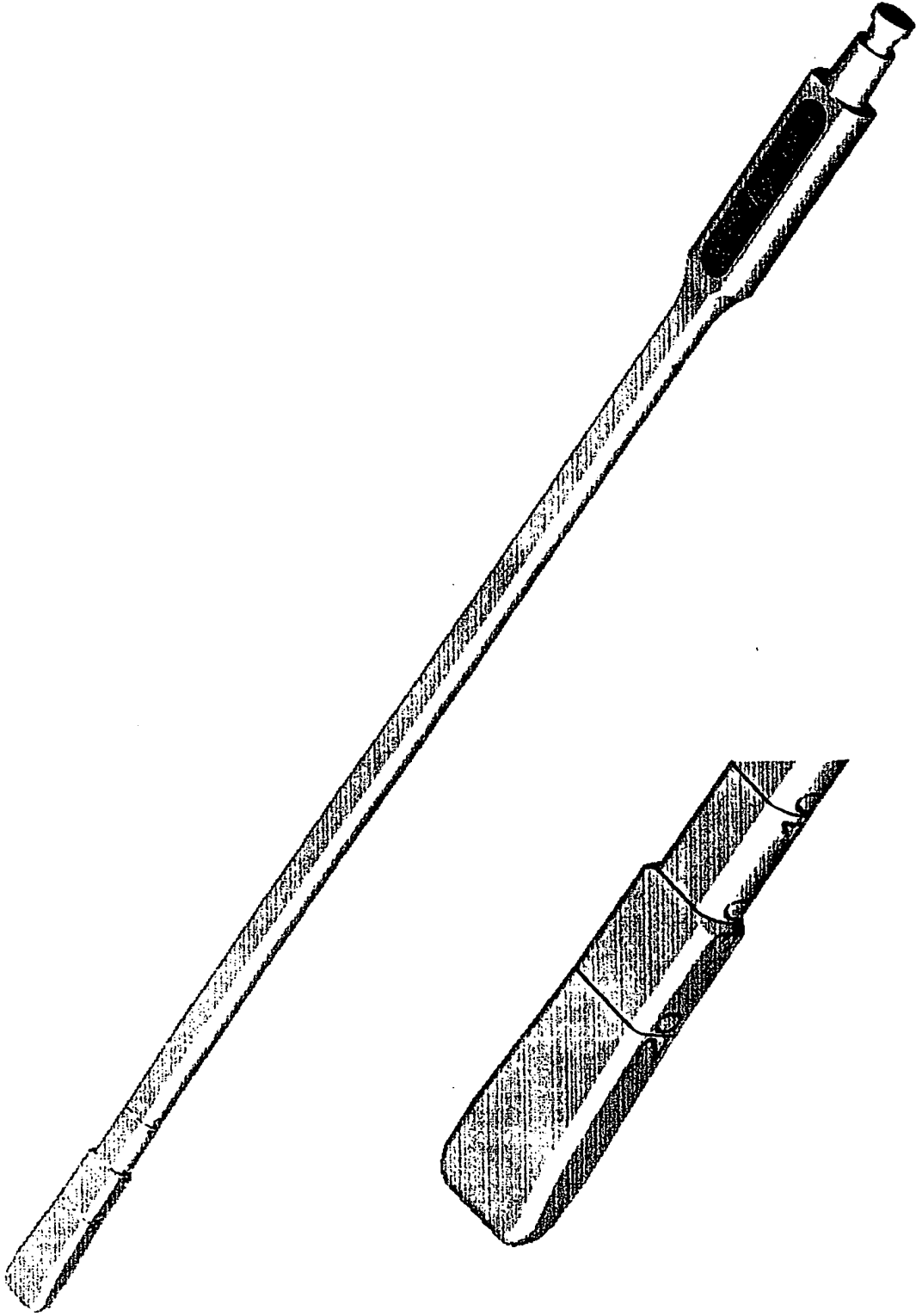
Retractor Blade



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Die distractor (turn-rotate)

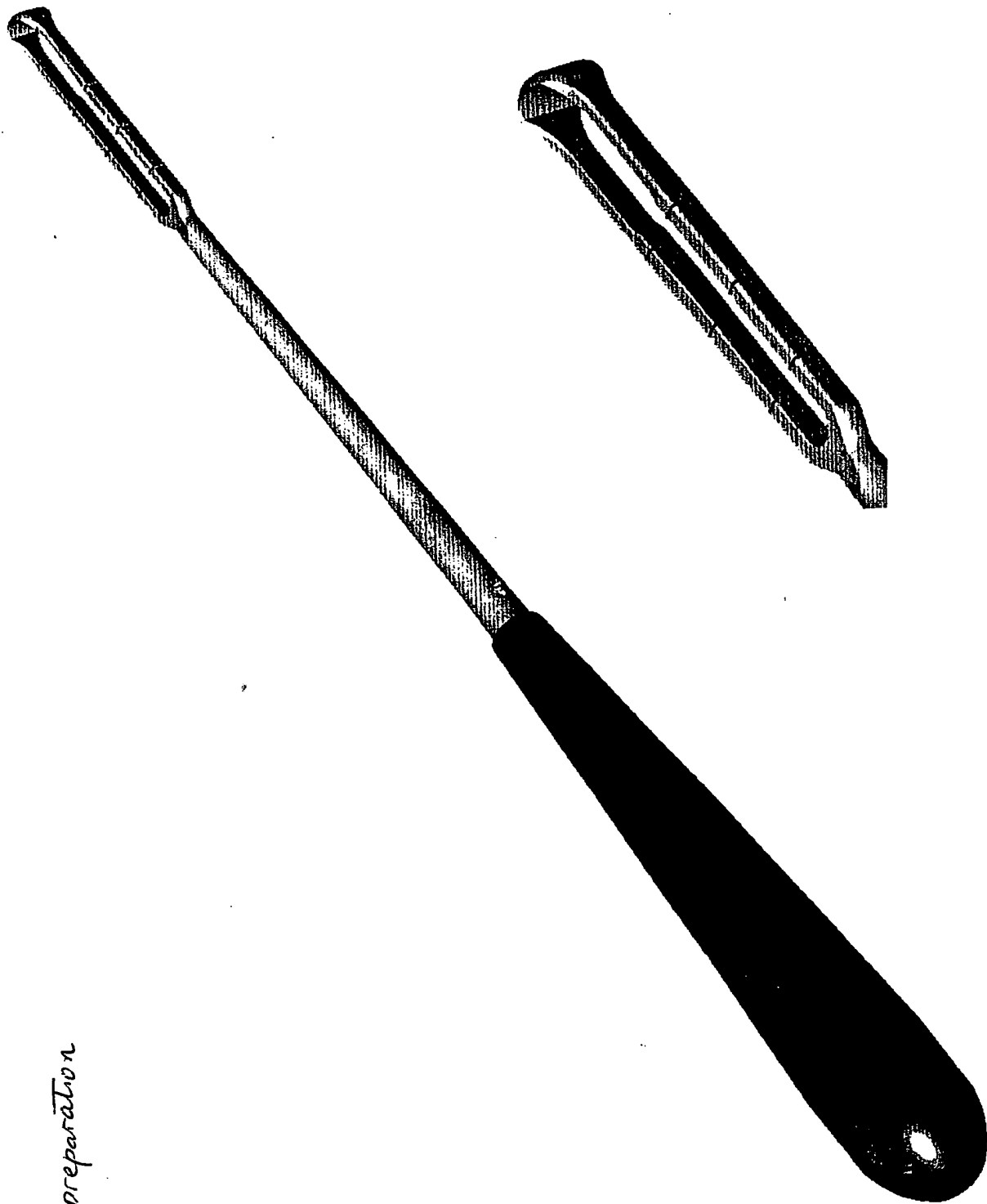


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Round Scraper

End plate preparation

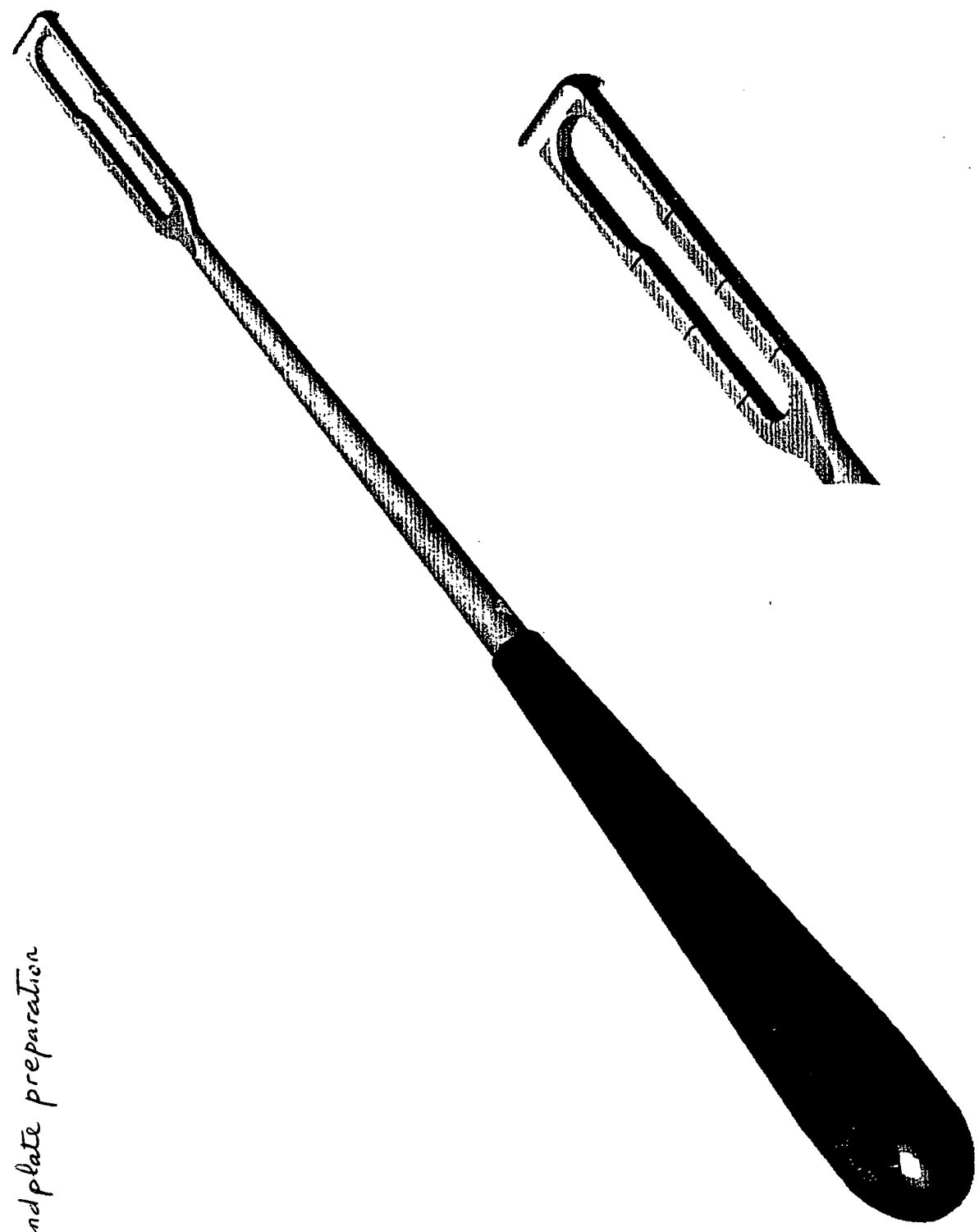


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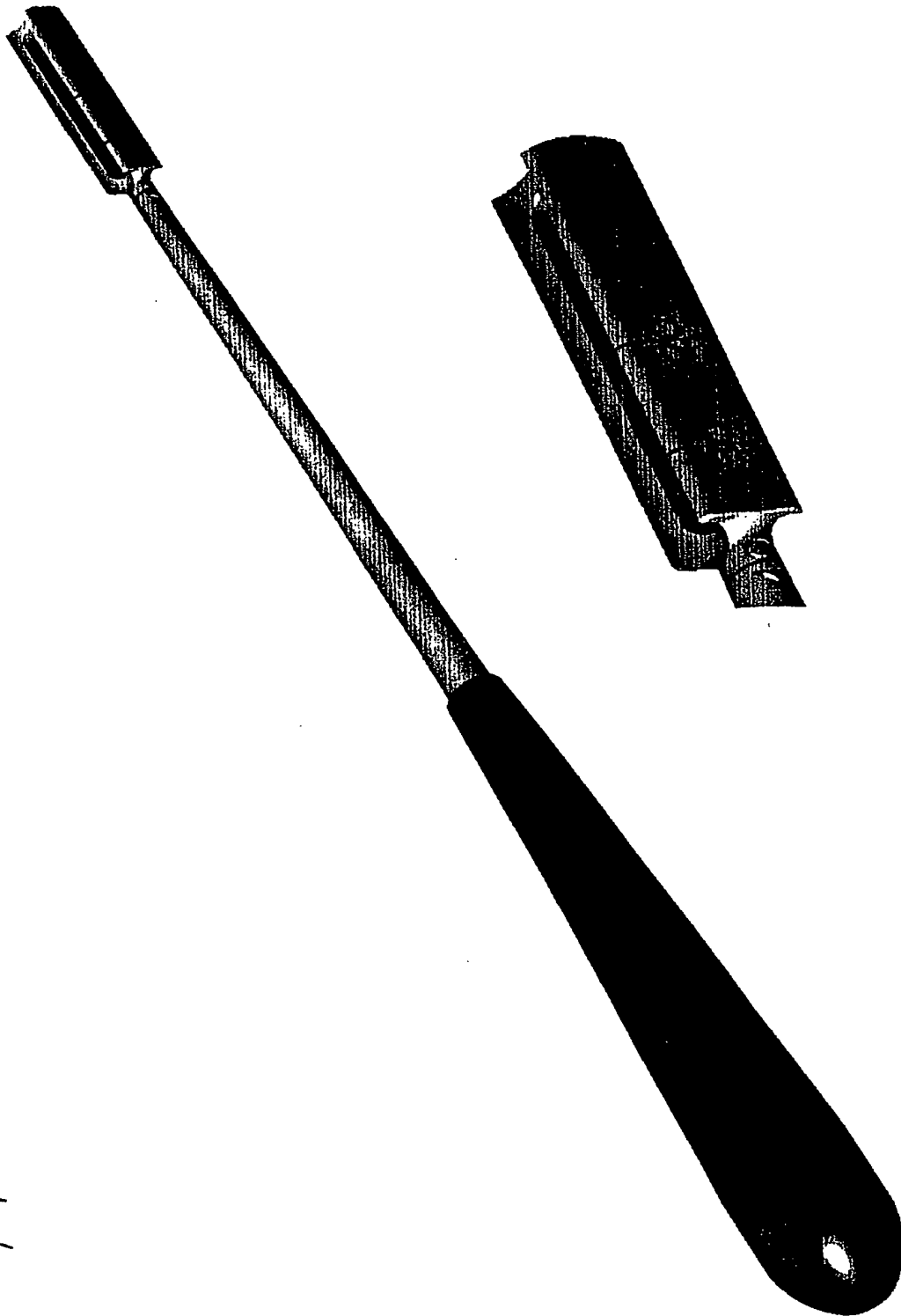
Plane Scraper
for endplate preparation



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Rotate cutter
for endplate preparation

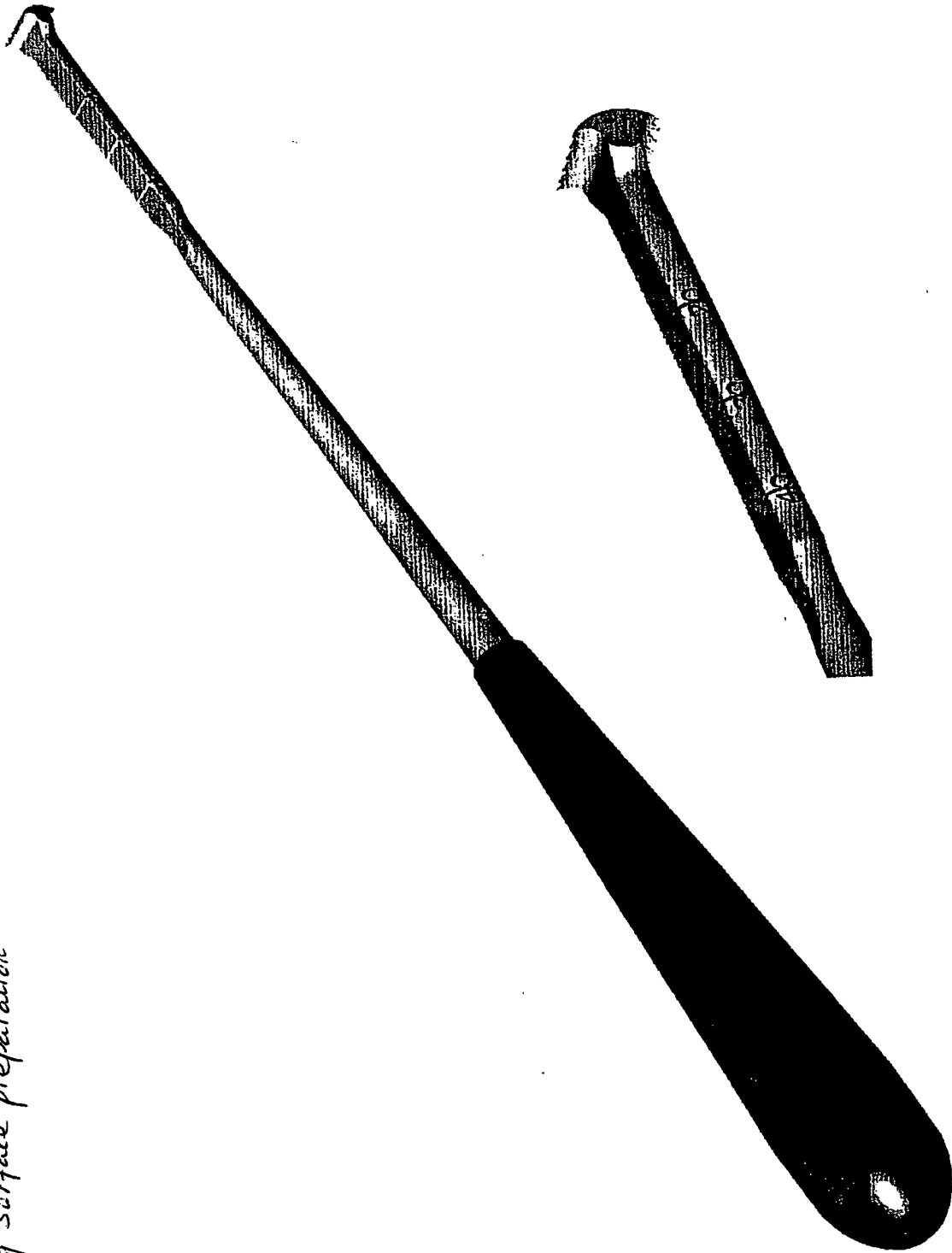


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Toothed Scraper

for bleeding surface preparation



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